Proposed Bioengineering Sciences and Technologies Integrated Review Group

Summary of Public Comments

The Bioengineering Sciences and Technologies (BST) Study Section Boundaries Team met November 6 - 9, 2001, to design study sections and to draft proposed guidelines that were made available for public comment on the Center for Scientific Review (CSR) Web page. The guidelines were posted for a twelve-week period that ended in March 2002.

In examining these comments, one should note that the study section guidelines created by the Study Section Boundaries Teams are recommendations to CSR. For recommendations to go forward they must be consistent with CSR policies and practices. For example, at this time, CSR and the Panel on Scientific Boundaries for Review are committed to no substantial changes in the neuroscience and behavioral science IRGs pending stabilization after their recent reorganization and formal evaluation.

Comments received are summarized below. General comments on this proposed IRG are presented first, followed by comments related to the structure or content of specific study sections and the expertise needed for them to function effectively.

General Comments

Bioengineering Community

- This seems like an excellent new plan.
- This type of review set-up is just what is needed. The study section descriptions along with the discussion of relationships between the study sections are right on the mark. The BST Study Section Boundaries Team has done an excellent job.
- The proposed changes would represent a significant improvement in the ability of NIH to fund cutting edge research in bioengineering and biological modeling.
- If implemented with appropriately chosen review panels, the proposed guidelines will generate a substantial number of proposals for NIH's consideration and subsequent significant research efforts on important topics.
- This seems to be a good idea because the advancement of bioscience or life science will increasingly depend on other supporting fields such as physics, chemistry, materials and engineering. The new BST IRG should

be focused on proposals that are aimed at providing new tools for life science and not on hypothesis driven proposals.

- Having previously struggled with an appropriate venue for review, Modeling and Analysis of Biological Systems (MABS) would be an appropriate home for a researcher who is currently developing a mathematical model of the menstrual cycle. The researcher hopes that this study section will be implemented and anticipates submitting proposals to it.
- Modeling of biological systems helps integrate data and provides structure for interpreting complex interactions and would benefit enormously from the opportunity to be funded as stand-alone research, especially model validation studies.

Imaging Community

- Members of the Imaging Community (as represented by the Academy of Radiology Research, the Society of Skeletal Radiologists, the American College of Radiology, the American Academy of Oral and Maxillofacial Radiology, and the American Osteopathic College of Radiology) echoed similar sentiments in their comments. They stated that extensive overlap exists between technology, methods, and applications and that applications should not be reviewed absent that context. In their view, the SSB Team's proposal places virtually all of imaging research into bioengineering and does not provide a basis for the correct classification and referral of imaging research proposals.
- Additionally, they stated that the guidelines were developed without adequate input from, or inclusion of, imaging scientists on the Boundaries Team. They have alternately proposed that CSR reorganize the BST and Surgery, Applied Imaging and Applied Bioengineering (SAIAB) IRGs, where one IRG would focus on surgery and bioengineering and the other upon biomedical imaging and computing. The latter IRG would include both basic and applied biomedical imaging.
- Finally, the members of the imaging community endorsed the idea that imaging and bioengineering be considered crosscutting areas and should be treated as exceptions to the general rule that recognizes the primacy of organ systems.

Genomics Community

- Several commenters whose applications are reviewed by the Genomics Study Section expressed concern for the movement of bioinformatics grant applications from the Genetic Sciences IRG into the BST IRG. They feel that it is essential that bioinformatics applications be reviewed alongside functional genomics and genetic applications. As one person stated, "the whole point of bioinformatics is to understand the biology." Thus, the members feel that having these applications reviewed in a study

section that also has significant expertise in biology is critical. Another commenter added that in order for computational biology to mature and fulfill its promise, attempts should be made to bring computation into every branch of biomedical research. In this opinion, such development will be hindered if CSR groups all bioinformatic proposals into a study section that focuses on data management and analysis issues separate from the biological issues.

- Another commenter was uncomfortable with labeling the IRG as a "Bioengineering" one. In her opinion, the best applicants and reviewers will not necessarily consider themselves "engineers." It was also unclear to her what will happen to the Bioanalytical Engineering and Chemistry (BECM) Study Section.

Comments on Specific Study Sections

Biodata Management and Analysis Study Section

CSR received comments concerning the treatment of applications within the subject area of bioinformatics. Under the proposed guidelines, those applications would be assigned to the Biodata Management and Analysis Study Section (BDMA):

- The idea (of the BDMA study section) is ill conceived because it promotes the notion that bioinformatics is somehow decoupled from the experiments. While there are very clear areas in which bioinformatics and biotechnology grant applications should be separated into a distinct category for review, there is absolutely no situation where a functional genomics application should be reviewed without careful consideration of the informatics support and infrastructure. The best applications have been those in which the development of new bioinformatics tools for data analysis, visualization and display were driven by the experimental program.
- It is a huge mistake to move bioinformatics and genomic technologies out of the Genome study section and into the new BST IRG. These approaches are inseparable from the biology of the studies that use them and will be impossible to evaluate effectively outside this context.
- The importance of real-life applications, such as in Biomedicine, require a synthesis of the ideas of both technology development/bioinformatics and genetics/genomics require a synthesis of all these ideas and separating them will create communities with no real appreciation of the science in the other. This may be an "efficient" way to conduct reviews, but will destroy the underlying synergy needed.
- Separation of bioinformatics and genomics would take the analytical work away from the biological sciences, decreasing the chances that useful work will be done. Second, it is far from clear that such a study section would reach out to first-rate workers in the field which includes several

varieties of statisticians, applied mathematicians, computer scientists and others, who have virtually no contact with the field of bioengineering science.

- Making BDMA equal to bioinformatics and MABS to computational biology creates a dangerous split. It would separate the analysis of genome-wide data sets, such as mRNA expression data, from the model of gene regulation. These areas need to be integrated, not split into separate disciplines.
- The only serious issue that I have with the BDMA study section is that it needs to contain leading bioinformatics researchers with a broad perspective on the field. No one listed on the SSB Team roster is a real bioinformaticist, although that doesn't preclude putting a strong study section together.
- There needs to be a clear delineation between bioinformatics and cell modeling type mathematical biology.
- It could be difficult to make a distinction where to place the bioinformatics proposals targeting both modeling and large-scale data analysis, to BDMA or to MABS. For instance, developing new methods of protein function prediction have a strong modeling component while being intended for application to large-scale data analysis.

Instrumentation and Systems Development (ISD)

- Based upon the sentence: "Although a test biological problem may be used to provide context, proposals to this study section need not be hypothesis driven", the commenter noted that it is extremely important that instrumentation be developed to solve important technical or fundamental problems in biology and not for the sake of just developing new technology. The long funding cycle that NIH provides should be used to entice engineers to fully understand the current laboratory capabilities and limitations before suggesting a new instrument.
- I urge the establishment of the proposed instrumentation and systems development study section. From personal experience, in spite of multiple institutes asserting the need for new technology and the desire to support the development of such, the present study sections still tend to judge proposed research in these areas as subordinate to hypothesis-driven research and score it accordingly.
- In the Analytical Instrumentation section, it would be wise to broaden the imaging technology beyond those listed. For example, novel absorbance, light scanner and other forms of optical microscopy could be quite valuable.
- I feel very strongly that the ISD Study Section, containing mainly Analytical Chemistry, belongs in the Biophysical and Chemical Sciences IRG. Analytical Chemistry is a branch of the Science of

Chemistry, and its applications should be reviewed in the same IRG as all other applications in Chemistry are reviewed.

- I support the creation of this new review group. My previous reviews were strongly supportive of the merit and ideas and promise of technology, but my proposals were rejected. That perspective matches the excitement in the scientific community for this new direction. Yet, the proposals were rejected because their application to biological systems had not been demonstrated.

Modeling and Analysis of Biological Systems (MABS)

- The guidelines appear too compartmentalized, restrictive and some elaboration upon Shared Interests is needed. For example, MABS includes among other subjects: integration of modeling and experiment, experimental validation of models and development, and adaptation of mathematical methods. If a proposal that is bioengineering in nature is doing that, but is in a cardiovascular field and is not defined as such through the Shared Interest Inside/Outside of the IRG (e.g., IRG 15 deals with devices such as stents, heart valves, vascular grafts and others in which modeling, application of mathematical methods and experimental validation are essential), this would possibly exclude such a proposal from being reviewed.
- I have several points: 1) In general, many biologically-based pharmokinetic or toxicokinetic models are hypothesis driven. They often do not have immediate practical use, but their frequent purpose is to improve the risk assessment process by reducing uncertainty in extrapolation. 2) It seems that even if the number of applications is not large enough, the MABS and BDMA study sections are not easy to combine because the data management and analysis is much different than understanding the chemical kinetics and dynamics well enough to describe the pharmokinetics and beneficial or deleterious effects. BDMA focuses on ways to handle the data and MABS focuses on ways to handle the relationships between measurements. 3) There may be some additional ways to differentiate between MABS and SAIAB than whether the work has a clinical or medical application or not. It seems that SAIAB is instrumentation-oriented and MABS would be mammalian-system oriented.
- The scope of MABS seems overly narrow, especially given the stated aim. The "Modeling methods" doesn't mention adaptive systems tools (the study of how and why biosystems change/evolve/learn is very important) or modern tools for trying to understand complexity (e.g. neurofuzzy systems).
- The "Specific models of important processes" seems focused on reductionist approaches at the molecular and cellular level, without the challenge of the "integrative" focus of the continuum from molecular to

organ/function that National Institute of Biomedical Imaging and Bioengineering (NIBIB) was expected to embrace.
- The delineation with IRG 21 (modeling with medical/clinical application) is noted, the scope of modeling/analysis as a tool for understanding complex biosystems is still too narrow and may deter some from writing proposals. Wording matters.

Other Comments

- At the bottom of page 6 and the top of page 7, the Health of the Population IRG was incorrectly identified as equivalent to the SNEM-3 study section. One study section is not an IRG. SNEM-5 is the study section that handles the applications oriented toward biostatistics and the development of new methods. SNEM-3 does demographic approaches to biomedical phenoma.
- I believe that this new IRG is required for advancement. Because there was no previous home for potential projects, I have had to develop relationships with parties uninterested in funding long-term projects with no immediate profitability. I feel that I would be more productive to my own institution if funding could be procured through NIH.
- There was no mention of vibrational spectroscopic (IR and Raman) microscopic imaging. There are applications to molecular composition (chemical structure) imaging that several labs are pursuing. Additionally, biophysical property imaging is also possible through the well-known sensitivity of vibrational spectra to such factors as hydration, hydrogen bonding and mechanical deformation.